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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,374

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Ralph Schneider

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12/21/2010

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,374	Applicant(s) SCHNEIDER ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,27,29-32,35-37 and 39-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,27,29-32,35-37 and 39-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the third Request for Continued Examination based on the 10/725374 application filed December 3, 2003. Claims 26, 27, 29-32, 35-37, and 39-50 as amended and newly presented in the response filed October 3, 2010 are currently pending and considered below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The examiner is unable to distinguish the intended limitation of the phrase "than the portion of the catheter shaft at the bending section is proximal to the balloon." For examination purposes, the examiner has interpreted the phrase to mean "than the portion of the catheter shaft proximal to the balloon."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 26, 29, 30, 41-43, 45, and 47-49 as best understood by the examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2002/0177800 A1 to Bagaoisan et al.

Regarding claim 26, Bagaoisan et al disclose a catheter comprising: a catheter shaft (44) having a distal end and a proximal end (see Fig. 2B reproduced below), the proximal end including a bending section (portion containing spiral cuts 60 to where the shaft enters the balloon) extending distally from the proximal end toward but not to the distal end, the bending section comprising one or more spiral cuts in the catheter shaft (60), the bending section having a flexibility greater than the flexibility of the portion of the catheter shaft adjacent the bending section (proximal of the beginning of cut 60); a balloon (12) secured to the distal end (74) of the catheter shaft so as to be spaced apart distally from the bending section (the examiner notes the distal securement point of the balloon is located distal of and separate from the bending section), the flexibility of the catheter shaft adjacent the balloon being lesser than the flexibility of the catheter shaft at the bending section (the catheter shaft adjacent the balloon at 74 has no spiral cuts and is therefore less flexible than portions with spiral cuts); a fitting (86) secured to the proximal end of the catheter shaft, the fitting including a passageway in fluid communication with the catheter shaft (fits the catheter shaft); and a fluid impermeable covering extending from the bending section toward but not to the distal end of the catheter shaft to seal the bending section (62).

Regarding claims 29 and 30, Bagaoisan et al disclose that the number of spiral sections is selectable (as a number of spiral sections had to be chosen, or selected, prior to manufacture), and that the fluid impermeable covering is shaped as a tube (62).

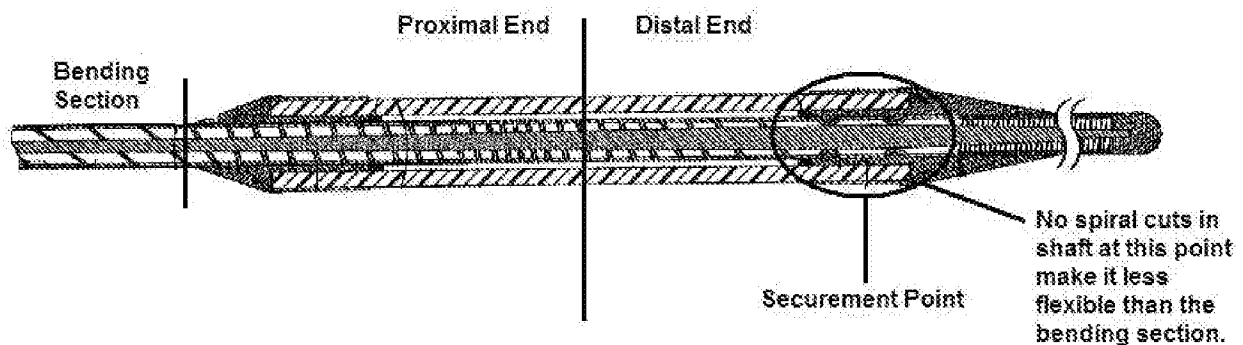
Regarding claim 41, Bagaoisan et al disclose a catheter comprising: a catheter shaft (44) having a distal end, a proximal end (see Fig. 2B below), and a first outer cross-sectional diameter (shaft outer diameter), the proximal end including a bending section (portion containing spiral cuts 60 to where the shaft enters the balloon), the bending section extending distally from the proximal end toward but not to the distal end, the bending section comprising one or more cuts in the catheter shaft (60), the bending section having a flexibility greater than the flexibility of the portion of the catheter shaft adjacent the bending section (proximal of the beginning of cut 60); a balloon (12) secured to the distal end (74) of the catheter shaft so as to be spaced apart distally from the bending section (the examiner notes the distal securement point of the balloon is located distal of and separate from the bending section), the flexibility of the catheter shaft adjacent the balloon being lesser than the flexibility of the catheter shaft at the bending section (the catheter shaft adjacent the balloon at 74 has no spiral cuts and is therefore less flexible than portions with spiral cuts); a fitting (86) secured to the proximal end of the catheter shaft and having a second inner cross-sectional diameter greater than the first outer cross-sectional diameter (shaft 44 fits within the fitting, therefore the inner cross-sectional diameter of the fitting must be greater than the outer cross-sectional diameter of the shaft); and a fluid impermeable covering extending from

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the bending section toward but not to the distal end of the catheter shaft to seal the bending section (62).

Regarding claims 42, 43, and 45, Bagaoisan et al further disclose that the one or more cuts are spiral cuts (60), that the fitting comprising a transition member (tapered portion) coupled to the catheter shaft, and that the device further includes an inflation device coupled to the fitting (20).

Regarding claims 47-49, Bagaoisan et al further disclose that the catheter shaft has a lumen (50) and the fitting is in fluid communication with the lumen [0057], that the portion of the catheter shaft adjacent balloon (at attachment point 74) has lesser flexibility than the portion of catheter shaft at the bending section is proximal to the balloon (there are no spiral cuts in the portion of the shaft attached to the balloon at point 74 and therefore it is less flexible than any point containing a spiral cut), and that the bending section has a flexibility greater than the flexibility of the portion of the catheter shaft adjacent and distal to the bending section (the portion of catheter shaft adjacent the bending section includes the portion of the shaft which is attached to the balloon, which has no spiral cuts and is therefore less flexible).



Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 27, 32, 35-37, 39, 40, 44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al.

Regarding claims 27 and 46, Bagaoisan et al teach all of the limitations of claims 26 and 41 as described above, but fail to teach that the fitting is a luer fitting. However, Bagaoisan et al teach the use of luer fittings (for example, 204) at the proximal end of other embodiments of their invention, and therefore, at the time of invention, it would have been obvious to one having ordinary skill in the art to attach a fitting having the form of a luer to the proximal end of the embodiment of Figure 2B in order to enable its connection to a multitude of standard medical injectors.

Regarding claims 32 and 44, Bagaoisan et al teach all of the limitations of claims 26 and 43 as described above, but fail to teach that the transition member extends over the proximal end of the catheter shaft and the proximal portion of the bending section. The examiner has noted that the tapered portion of Bagaoisan et al, having a smaller diameter as shown in Figure 3, constitutes the transition member. At the time of invention, it would have been obvious to one having ordinary skill in the art to place the bending section (containing spiral cut(s) 60) shown at any portion of the catheter where additional flexibility was desired, including at the most extreme proximal end of the device, such that a portion of the bending section is at the proximal terminus of catheter shaft 44 and thus inserted into the transition member. Such a configuration would allow for flexibility in the placement of the fitting 86 with respect to the patient when the device is in use.

Regarding claim 35, Bagaoisan et al teach a catheter comprising: a fitting including a passageway (86); a catheter shaft (44) including a distal end and a proximal end (See Fig. 2B below), the proximal end being coupled to the fitting (Fig. 3), which is

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in fluid communication with the catheter shaft (catheter shaft passes through the fitting), the proximal end including a bending section extending distally from the proximal end toward but not to the distal end (portion containing spiral cuts 60 to where the cuts begin to increase in pitch), the bending section comprising one or more cuts in the catheter shaft (60), the bending section having a flexibility greater than the flexibility of the remainder of the catheter shaft (proximal of the beginning of cut 60); a fluid impermeable covering extending from the bending section toward but not to the distal end of the catheter shaft to seal the one or more cuts of the bending section (62), and a balloon (12) secured to the distal end (74) of the catheter shaft so as to be spaced apart distally from the bending section (the examiner notes the distal securement point of the balloon is located distal of and separate from the bending section), the flexibility of the catheter shaft adjacent the balloon being lesser than the flexibility of the catheter shaft at the bending section (the catheter shaft adjacent the balloon at 74 has no spiral cuts and is therefore less flexible than portions with spiral cuts). Bagaoisan et al fail to explicitly teach that a proximal portion of the fluid impermeable covering is located within the passageway of the fitting, however, the examiner notes that the cuts and therefore the fluid impermeable covering can be located or extend along any length of the catheter to impart the desired flexibility, and as such could be located at the extreme proximal terminus of the shaft 44, and thus within the passageway of the fitting 86.

Regarding claims 36 and 39, Bagaoisan et al teach that the cut is a spiral cut (60) and that the cuts increase in pitch towards the distal end (Fig. 2A).

Regarding claim 37, see above rejection of claims 32 and 44.

Regarding claim 40, see above rejection of claims 27 and 46.

Regarding claim 50, the examiner notes that the spiral cut of Bagaoisan et al imparts flexibility to the cut portion and as such, additional flexible portions along the length of the catheter may be desired [136] which would require the fluid impermeable covering (62) so as to not leak the inflation fluid prior to reaching the balloon, and as such, would have a fluid impermeable covering extending distally toward, but not to, the balloon.

10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al in view of USPGPub 2004/0127934 A1 to Gilson et al.

Regarding claim 31, Bagaoisan et al teach all of the limitations of claim 26 as described above, but fail to teach or disclose that the impermeable covering is adhesively bonded to the bending section, instead teaching a heat shrink covering. However, Gilson et al teach using an adhesive in addition to heat shrink covering (Paragraph [0234]). At the time of invention, it would have been obvious to one having ordinary skill in the art to use adhesive, in addition to the heat shrinking cover of Bagaoisan et al in order to ensure a firm hold and guarantee fluid imperviousness.

Response to Arguments

11. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763